Patent SYR-DPP-IV-5004-C2



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Group Art Unit: 1624

Jun Feng et al.

Examiner: Not Yet Assigned

Serial No.: 10/809,637

Filed: March 24, 2004

For: DIPEPTIDYL PEPTIDASE

**INHIBITORS** 

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Supplemental Information Disclosure Statement ("SIDS") are brought to the attention of the Office. The items are listed on the attached form PTO-1449, and copies of the literature and non-U.S. patent references are included. As the Office no longer requires copies of U.S. patents and applications, the U.S. copies are not being submitted with this SIDS. However, if the Examiner would like copies of the U.S. cited references, Applicants will provide the references upon request.

The items identified in this SIDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicants as such.

## INFORMATION DISCLOSURE STATEMENT FILING PROVISION:

$\boxtimes$		IDS is believed to be timely in that it is being submitted under 37 CFR §
•	•	is (1) within three months of the filing date of the application, which is not a
	•	osecution application filed under § 1.53(d); or (2) within three months of attional stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a
•		tion on the merits; or (4) before the mailing of a first Office action after filing
		continued examination under § 1.114. Thus, no fee is required.
	$\boxtimes$	However, if the undersigned is in error in this regard, Applicant respectfully
		requests that the Office consider this SIDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR §1.17(p) to the deposit account referenced below.
		However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this SIDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.
	This S	IDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a
first O	ffice ac	tion on the merits, but before a Final Action under 37 CFR § 1.113 or a
Notice	of Allo	owance under 37 CFR § 1.311.
		The fee due under 37 CFR § 1.17(p) is submitted herewith.
		A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this SIDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.
payme	37 CFI ent of th	IDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action R § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before he issue fee. A statement under 37 CFR § 1.97(e) is included below. The r 37 CFR § 1.17(p) is submitted herewith.
		STATEMENT UNDER 37 CFR § 1.97(e):
	Each i	tem contained in this SIDS was first cited in any communication from a
foreigr	n paten	t office in a counterpart foreign application not more than three months
prior to	the fil	ing of this SIDS.
	No ite	m contained in this SIDS was cited in a communication from a foreign
oatent	office i	in a counterpart foreign application, and, to the knowledge of the person

signing this statement after making reasonable inquiry, no item of information contained in this SIDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this SIDS.

	PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:
	A check in the amount of is enclosed for the above fee(s).
	Please charge to Deposit Account No. 50-2256 for the above fee(s).
	Although Applicants do not believe any fees are required, the Commissioner is rized to charge any fees required by the filing of these papers to Takeda's Deposit ant No. 50-2256.
	Respectfully submitted,
	TAKEDA SAN DIEGO, INC.
Dated	By: David J. Weitz Reg. No. 38,362

Customer No. **32793**Takeda San Diego, Inc.
10410 Science Center Drive
San Diego, CA 92121
Take (950) CO2 9520

Tel: (858) 622-8528 Fax: (858) 550-0992

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

AUG 0 2 2005

Substitute for form 1449A/PTO Complete if Known 10/809,637 **Application Number** INFORMATION DISCLOSURE March 24, 2004 Filing Date STATEMENT BY APPLICANT First Named Inventor Jun FENG Group Art Unit 1624 (use as many sheets as necessary) **Examiner Name** Sheet Attorney Docket Number SYR-DPP-IV-5004-C2

			U.S. PATENT	OCUMENTS	
Examiner	Cite	Document Number	Publication Date/	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant
Initials *	No.'	Number - Kind Code <sup>2</sup> (if known)	Issue Date MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear
	AA	US1998/5798344	12-25-1998	Kuroki et al.	
	AB	US2002/0169159	11-14-2002	Medina et al.	
	AC	US2003/0069234	4-10-2003	Medina et al.	

		FOREIGN PA	TENT DOCU	MENTS		
	Foreign Patent Document			Pages, Columns, Lines, Where		
Examiner Initials*	Cite No.¹	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	T⁴
	AD	BR 699812	11-29-1950	The Distillers Company Limited		
	AE	53005180 A	01-18-1978	Sumitomo Chem		
	AF	EP 1136482 A1	09-26-2001	Sanofi-Synthelabo		
	AG	WO 01/96295 A2	12-20-2001	Novartis AG		
	AH	WO 02/02560 A2	01-10-2002	Novo Nordisk		
-	Al	WO 03/000181 A2	01-03-2003	Merck & Co., Inc.		
	AJ	WO 03/007888 A2	01-30-2003	Adipogenix, Inc.	·	
	AK	WO 03/027080 A1	04-03-2003	Mitsubishi Pharma		
	AL	WO 03/037888 A1	05-08-2003	Mitsubishi Pharma		
	AM	WO 03/076418 A1	09-18-2003	X-Ceptor Therapeutics, Inc.		
	AN	WO 04/062613 A2	07-29-2004	Bristol-Myers Squibb		
	AO	WO 04/085408 A1	10-07-2004	Mitsubishi Pharma		

Examiner	Date	
Signature	Considered	J

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO	Complete if Known		
	Application Number	10/809,637	
INFORMATION DISCLOSURE	Filing Date	March 24, 2004	
STATEMENT BY APPLICANT	First Named Inventor	Jun FENG	
	Group Art Unit	1624	
(use as many sheets as necessary)	Examiner Name		
Sheet 2 of 2	Attorney Docket Number	SYR-DPP-IV-5004-C2	

	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>			
	АР	DEY, PARAMITA D., et al., Regioselective [4+2] Cycloaddition versus Nucleophilic Reactions of N-Arylamino Substituted 1,3-Diaza-1,3-Butadienes with Ketenes: Synthesis of Pyrimidinone and Fused Pyrimidione Derivatives. Part II. Tetrahedron, Vol. 53, No. 40, pp. 13829-13840, 1997.				
	AQ	JAKUBKIENE, VIRGINIJA, et al., (G-Methyl-2methylsulfanyl-4-oxo-3,4-dihydro-3-pyrimidinyl)acetic acid and related compounds exhibiting anti-inflammatory activity. Pharmazie 57 (2002) 9, pp. 610-613.				
	AR	JONES, TERENCE R., et al., Azafluorenes Containing Two Bridgehead Nitrogen Atoms. Journal of the Chemical Society, Perkin Transactions 1, No. 12, December 1987, pp. 2585-2592.				
	AS	SHARMA, ARUN K., et al. Tandem sigmatropic shifts in [4 + 2] cycloaddition reactions of 1,3-diazabuta-1,3-dienes with butadienylketene: synthesis of pyrimidinone derivatives. J. Chem. Soc., Perkin Trans. 1, 2002, 774-784.	•			
	АТ	Database Crossfire Beilstein Institut Zur Foerderung Der Chmischen Wissenschaften. XP-002310120. Beilstein Registry Number 638238 & Synthetic Procedures in Nucleic Acid Chemistry, Vol. 1, 1968, page 92.				
	AU	Database Crossfire Beilstein Institut Zur Foerderung Der Chmischen Wissenschaften. XP-002310119. Beilstein Registry Number 649497 & J. Pharm. Sci. Vol. 80, No. 7, 1991, pp. 705-706.				
	AV	Database CA Online Chemical Abstracts Service, Columbus, OH, US; Troschuetz, Reinhard et al., The reaction of O-functional benzylmalononitriles with N-bisnucleophiles as well as alcoholates, XP-002311761 retrieved from STN Database accession No. 1994:217538 abstract & Archiv Der Pharmazie (Winheim, Germany), 326(11), 865-9 Coden: ARPMAS; ISSN: 0365-6233, 1993.				
	AW	Database Crossfire Beilstein Institut Zur Foerderung Der Chmischen Wissenschaften. XP-002310121. Beilstein Registry Number 7289032 & Nucleosides Nucleotides, Vol. 14, No. 3-5, 1995, pp. 653-656.				
	AX	Database Crossfire Beilstein Institut Zur Foerderung Der Chmischen Wissenschaften. XP-002310118. Beilstein Registry Number 7643826 & KHIM. Geterotsikl. Soedin., Vol. 32, No. 5, 1996, pp. 703-707.				
	AY	Database Crossfire Beilstein Institut Zur Foerderung Der Chmischen Wissenschaften. XP-002310117. Beilstein Registry Number 8373244 & KHIM. Geterotsikl. Soedin., No. 8, 1998, pp. 1125-1129.				

Examiner	Date	
Signature	Considered	j

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 199 persons are reported to respond to a collection of information unless it contains a valid OMB control number.

AUG 0 2 2005

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known					
Application Number	PCT/US2004/026265				
Filing Date	08/12/2004				
First Named Inventor	FENG				
Group Art Unit	·				
Examiner Name					
Attorney Docket Number	SYR-DPP-IV-5013-U				

			U.S. PATENT	OCUMENTS	
Examiner	Cite	Document Number	Publication Date/	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant
Initials *	No.1	Number - Kind Code <sup>2</sup> ( <i>if known</i> )	Issue Date MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear
	AA	US1998/5798344	12-25-1998	Kuroki et al.	,
	AB	US2002/0169159	11-14-2002	Medina et al.	•
	AC	US2003/0069234	4-10-2003	Medina et al.	

		FOREIGN PA	TENT DOCU	MENTS		
	Foreign Patent Document				Pages, Columns, Lines, Where	
Examiner Initials*	Cite No. <sup>1</sup>	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited  Document  .	Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	AD	BR 699812	11-29-1950	The Distillers Company Limited		
,	AE	53005180 A	01-18-1978	Sumitomo Chem		
	AF	EP 1136482 A1	09-26-2001	Sanofi-Synthelabo		
	AG	WO 01/96295 A2	12-20-2001	Novartis AG		
	AH	WO 02/02560 A2	01-10-2002	Novo Nordisk		
	Al	WO 03/000181 A2	01-03-2003	Merck & Co., Inc.		
	LA	WO 03/007888 A2	01-30-2003	Adipogenix, Inc.		
	AK	WO 03/027080 A1	04-03-2003	Mitsubishi Pharma		
	AL	WO 03/037888 A1	05-08-2003	Mitsubishi Pharma		
	AM	WO 03/076418 A1	09-18-2003	X-Ceptor Therapeutics, Inc.		
	AN	WO 04/062613 A2	07-29-2004	Bristol-Myers Squibb		
	AO	WO 04/085408 A1	10-07-2004	Mitsubishi Pharma		

Examiner	Date	
Signature	Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO					Complete if Known		
					Application Number	PCT/US2004/026265	
INFORMATION DISCLOSURE					Filing Date	08/12/2004	
STATEMENT BY APPLICANT					First Named Inventor	FENG	
				1	Group Art Unit		
(use as many sheets as necessary)					Examiner Name		
Sheet	2	of	2		Attorney Docket Number	SYR-DPP-IV-5013-U	

OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS						
Examiner Cite Initials * No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				
	AP	DEY, PARAMITA D., et al., Regioselective [4+2] Cycloaddition versus Nucleophilic Reactions of N-Arylamino Substituted 1,3-Diaza-1,3-Butadienes with Ketenes: Synthesis of Pyrimidinone and Fused Pyrimidione Derivatives. Part II. Tetrahedron, Vol. 53, No. 40, pp. 13829-13840, 1997.				
	AQ	JAKUBKIENE, VIRGINIJA, et al., (G-Methyl-2methylsulfanyl-4-oxo-3,4-dihydro-3-pyrimidinyl)acetic acid and related compounds exhibiting anti-inflammatory activity. Pharmazie 57 (2002) 9, pp. 610-613.				
	AR	JONES, TERENCE R., et al., Azafluorenes Containing Two Bridgehead Nitrogen Atoms. Journal of the Chemical Society, Perkin Transactions 1, No. 12, December 1987, pp. 2585-2592.				
	AS	SHARMA, ARUN K., et al. Tandem sigmatropic shifts in [4 + 2] cycloaddition reactions of 1,3-diazabuta-1,3-dienes with butadienylketene: synthesis of pyrimidinone derivatives. J. Chem. Soc., Perkin Trans. 1, 2002, 774-784.				
	AT	Database Crossfire Beilstein Institut Zur Foerderung Der Chmischen Wissenschaften. XP-002310120. Beilstein Registry Number 638238 & Synthetic Procedures in Nucleic Acid Chemistry, Vol. 1, 1968, page 92.				
	AU	Database Crossfire Beilstein Institut Zur Foerderung Der Chmischen Wissenschaften. XP-002310119. Beilstein Registry Number 649497 & J. Pharm. Sci. Vol. 80, No. 7, 1991, pp. 705-706.				
	AV	Database CA Online Chemical Abstracts Service, Columbus, OH, US; Troschuetz, Reinhard et al., The reaction of O-functional benzylmalononitriles with N-bisnucleophiles as well as alcoholates. XP-002311761 retrieved from STN Database accession No. 1994:217538 abstract & Archiv Der Pharmazie (Winheim, Germany), 326(11), 865-9 Coden: ARPMAS; ISSN: 0365-6233, 1993.				
	AW	Database Crossfire Beilstein Institut Zur Foerderung Der Chmischen Wissenschaften. XP-002310121. Beilstein Registry Number 7289032 & Nucleosides Nucleotides, Vol. 14, No. 3-5, 1995, pp. 653-656.				
	AX	Database Crossfire Beilstein Institut Zur Foerderung Der Chmischen Wissenschaften. XP-002310118. Beilstein Registry Number 7643826 & KHIM. Geterotsikl. Soedin., Vol. 32, No. 5, 1996, pp. 703-707.				
	AY	Database Crossfire Beilstein Institut Zur Foerderung Der Chmischen Wissenschaften. XP-002310117. Beilstein Registry Number 8373244 & KHIM. Geterotsikl. Soedin., No. 8, 1998, pp. 1125-1129.				

	<del></del>		
Examiner	·	Date	
Signature		Considered	·

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.